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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,627	03/17/2004	Igor Rukhman	1662/63303	4926
26646	7590	03/08/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			CHUNG, SUSANNAH LEE	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,627	RUKHMAN ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,12-14,17,81 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-6,9,12-14,81 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 17 is pending in the instant application. Claims 2, 7, 10, 11, 15, 16, 18, 19-80 and 83-85 are canceled. Claims 1, 3-6, 8-9, 12-14, 81 and 82 are withdrawn as being drawn to non-elected subject matter.

Response

Applicant's Remarks and amendment to the claims filed on 12/19/2005 are acknowledged.

Claim 17 stands rejected under 35 USC 103 as obvious over U.S. Pat. No. 5,399,578 ('578 Patent). Claim 17 is directed to an "amorphous form of valsartan, wherein the amorphous form has a DSC thermogram that lacks a melting point above about 1 J/g."

Applicants state the following:

As the Examiner is aware, melting is the thermal disordering of a crystalline lattice. Therefore crystalline solids generally exhibit a melting point (some crystalline solids decompose before melting). However, the solid of the present invention, being purely amorphous, does not have any crystalline order. Therefore does not melt, and does not have a melting point. This lack of a melting point is demonstrated in the lack of any endothermic peak present in the DSC thermogram, Figure 3. (Since melting takes thermal energy, one would expect to see an endothermic peak at the melting point.)

According to the Office Action, the '578 patent discloses valsartan with a melting point of 105 to 115°C. ('578 patent, col. 34, l. 62). Because it exhibited a melting point, that valsartan was at least partially crystalline, and not completely amorphous.

It is true that crystalline solids generally exhibit a melting point, but it is also true that solids exhibit a melting point. The amorphous form, which is described by applicant as being devoid of crystalline structure, will also exhibit a melting point. The '578 Patent discloses an amorphous form with melting points. Unless applicant can demonstrate a patentable difference with the '578 Patent the instant claim is obvious in view of it.

An amorphous form of a compound is a solid in which there is no long-range order of the positions of the atoms. (Solids in which there is long-range atomic order are called crystalline solids.) Most classes of solid materials can be found or prepared in an amorphous form. Therefore, it is difficult to distinguish between amorphous forms because by their very nature there is no order to the position of the atoms and replication of amorphous forms will probably include variations based on methods of preparation, levels of impurity, amount of water, etc....

It should be noted that generally melting point is not a good measure of patentability because it varies greatly depending on the amount of impurity, water, etc... In addition, no patentable weight will be given to melting point unless a clear side-by-side comparison is done distinguishing the two compounds, i.e. showing the patentable aspect of the compound. Based on the data provided, it appears that one skilled in the art could produce the same amorphous form of the instant application, utilizing the methods disclosed in the '578 Patent.

Therefore, the instant claim, which discloses an amorphous form of valsartan, but not the melting point, is not allowable in view of the '578 Patent which also discloses an amorphous form of valsartan with the melting point.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

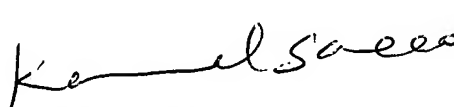
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
Patent Examiner, AU 1626
Date: 03/01/2006



KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER